

Section II (Remarks)**BEST AVAILABLE COPY**A. Summary of Amendment to the Claims

Claim 17 has been canceled herein, claims 1-11, 14, 18-23, 25, 28, 30, 31, 34, 37, 39-42, and 47-49 have been amended, and claims 80-87 are newly added to further patently delineate the subject matter recited therein.

The limitations introduced in the amended and new claims are fully consistent with and supported by the originally filed disclosure of the application. No new matter within the meaning of 35 USC § 132 has been added.

Independent claims 1 and 22 now recite, *inter alia*, “a base member; a first sheet of porous material joined along at least a first edge portion thereof to the base member to define an interior volume; a second sheet overlying and sealed to the first sheet; and a pressurization gas inlet adapted to permit the ingress of pressurization gas to the interior volume. Such amendatory changes are supported by the disclosure, for example, at page 7, paragraph [0021] (“pressurization integrity testing can be accommodated by providing a pressurization gas inlet ... to allow ingress of gas therethrough into the interior volume of the container package”); page 5, paragraph [0015] (“[t]he overlying sheet provides a non-porous barrier over the porous sheet ... [t]he overlying sheet can be a single layer or a it can be of multilayer character, formed for example by coextrusion and including a peelable layer and a non-porous backing layer”); and page 9, paragraph [0026] (porous material layer 26 and non-porous sheet [or base member] 28 joined by ultrasonic welding fusion bonding along their registered edges); Figs 1 and 2 and corresponding text.

Claims 2-11, 14, and 18-21 have been amended to recite a “packaging article” and, where applicable, to substitute “sheet” for layer. Ample support exists in the disclosure for such amendments.

Claims 23, 25, 28, 30, 31, 34, and 49 have been amended to substitute “sheet” for “layer.” Ample support exists in the disclosure for such amendments.

Claim 37 has been amended to recite that the base member comprises a non-porous structural component. Support exists in the disclosure for such amendments, for example, at page 6, paragraph [0017] (a sterilizable bag [is] constructed of a first sheet of a non-porous polymeric film, e.g., polyethylene film, and a facing sheet of a porous material”) and page 9, paragraph [0029] (“package 30 comprises a non-

porous package member 36 which can be of a tray or cassette form.”)

Claim 39 has been amended to recite that the non-porous structural component comprises a shaped member adapted to secure at least a portion of the product article therein. Support exists in the disclosure for such amendments, for example, at page 9, paragraph [0029] ([t]he package 30 comprises a non-porous package member 36 which can be of a tray or cassette form, defining a receptacle within which the catheter coupling assembly is disposed).

Claims 18, 40, and 47 have been amended to recite that the packaging article is in the form of a bag (e.g., adapted to hold a product article therein). Support exists in the disclosure for such amendment, for example, at page 6, paragraph [0017] (a sterilizable bag [is] constructed of a first sheet of a non-porous polymeric film, e.g., polyethylene film, and a facing sheet of a porous material”).

New claims 80-87 recite various details of the pressurization gas inlet. Support exists in the disclosure for such amendments, for example, at page 7, paragraph [0021].

Various compositional limitations that were added by prior amendment have been deleted as unnecessary to patentability of the claims amended herewith.

As thus amended, claims 1-11, 14, 18-31, 34 and 37-49 are now in form for allowance, consistent with the distinguishing remarks directed to such claims in the ensuing section.

B. Rejections Under 35 U.S.C. § 112, First Paragraph

In the December 28, 2005 Office Action, claims 1-11, 14, 17-31, 34, and 37-49 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, it was asserted that the claims contained subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding previously-pending claims 1 and 22, the examiner rejected the claims based on the limitations that the second layer “consists essentially of polyethylene” and the peelable film of the second layer “consists essentially of polyethylene.” Applicants respectfully disagree with the examiner’s conclusion that such limitations are not enabled. The examiner admits that the specification discloses that the

peelable sheet is desirably a peelable polyethylene sheet. December 28, 2005 Office Action, page 3. Based on such disclosure, limitations that the second layer and peelable film “consist essentially of polyethylene” are unquestionably enabled. Without conceding this point, Applicants have amended claims 1 and 22 herewith to eliminate the “consists essentially of polyethylene” limitations. In view of the presence of the newly added and patentably distinct “pressurization gas inlet” limitation, the polyethylene material limitations are not necessary to establish the patentability of claims 1 and 22.

Additionally with regard to previously-pending claims 1 and 22, the examiner rejected the claims based on the limitation that the second layer is sealed to the first layer “over its entire contacting surface.” Again, Applicants respectfully disagree with the examiner’s conclusion that such limitations are not enabled. See, e.g. application page 9, paragraph [0027] ([o]n the exterior face of the porous material layer 26 (the top surface in the view shown), is sealed the peelably removable sheet 18 ... including a first layer 24 of a peelable polymeric film material in facial contact with the porous material sheet 26”) and paragraph [0029]([t]he overlying sheet can be a coextruded sheet formed of a peel layer and a backing layer). With no indication that the peelably removable sheet has adhesive along only a peripheral portion thereof, one skilled in the art would reasonably assume that the peel layer of the second sheet is sealed over its entire face to the underlying first sheet. Without conceding this point, Applicants have amended claims 1 and 22 herewith to eliminate the “over its entire contacting surface” limitation. In view of the presence of the newly added and patentably distinct “pressurization gas inlet” limitation, the “over its entire contacting surface” limitation is not necessary to establish the patentability of claims 1 and 22.

With regard to previously-pending claims 14 and 34, the examiner rejected the claims based on the limitation that the backing layer “consists essentially of polyethylene.” Applicants respectfully disagree with the examiner’s conclusion that such limitations are not enabled. The examiner admits that the specification discloses that the backing material is for example polyethylene. December 28, 2005 Office Action, page 5. Based on such disclosure, limitations that the second layer and peelable film “consist essentially of polyethylene” are unquestionably enabled. Without conceding this point, Applicants have amended claims 14 and 34 herewith to eliminate the “consists essentially of polyethylene” limitations. In view of the presence of the newly added and patentably distinct “pressurization gas inlet” limitation, the polyethylene material limitations are not necessary to establish the patentability of claims 14 and 34.

C. Rejections Under 35 U.S.C. § 112, Second Paragraph

In the December 28, 2005 Office Action, claims 1-11, 14, 17-31, 34, and 37-49 were rejected under 35

U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter that applicants regard as the invention.

Regarding previously-pending claims 1 and 22, the examiner advanced multiple grounds for rejection under 35 U.S.C. 112, second paragraph.

The first rejection of previously-pending claims 1 and 22 under 35 U.S.C. 112, second paragraph related to “the second layer” – in particular, it was not understood how “the second layer” can be formed of multiple layers (such as provided in claim 14). December 28, 2005 Office Action, page 6. Consistent with the examiner’s suggestion, “the first layer” and “the second layer” have been replaced with “the first sheet” and “the second sheet,” respectively, in the amended claims. In this manner, it will be more definite that each sheet may include multiple layers – e.g., the second sheet may include a peelable film and a backing layer (such as provided in claim 14).

The second rejection of previously-pending claims 1 and 22 under 35 U.S.C. 112, second paragraph related to the “consisting essentially of” language in the claims, as conflicting with the “comprising language” in line of claim 1 and in line 8 of claim 22. December 28, 2005 Office Action, page 6. As indicated previously, the “consisting essentially of” language has been deleted from claims 1 and 22 by the amendments provided herewith.

The third rejection of previously-pending claims 1 and 22 under 35 U.S.C. 112, second paragraph related to the “in contact with and sealed to the first layer over its entire contacting surface” language of the claims, as it was not understood whether the limitation required the second layer be “in contact with the first layer over its entire contacting surface and sealed over that same surface” or required “the first and second layers are in contact with each other and that over the entire contacting surface the layers are sealed.” December 28, 2005 Office Action, pages 6-7. As indicated previously, the “in contact with and sealed to the first layer over its entire contacting surface” language of the claims has been deleted from claims 1 and 22 by the amendments provided herewith.

The fourth rejection of previously-pending claims 1 and 22 under 35 U.S.C. 112, second paragraph related to the term “its” as previously provided in line 4 of claim 1 and in line 7 of claim 22. The term “its” has been deleted from claims 1 and 22 by the amendments provided herewith.

With all of the rejections of previously-pending claims 1 and 22 under 35 U.S.C. 112, second paragraph

having been addressed by amendment of the claims, withdrawal of such rejections is respectfully requested.

Regarding previously-pending claims 14 and 34, the examiner rejected the claims under 35 U.S.C. 112, second paragraph as it was not understood how the second layer can "further comprise a backing layer" when the examiner opined that in claims 1 and 22 (on which claims 14 and 34 depend) "the second layer [was] limited in scope to be partially closed." December 28, 2005 Office Action, page 7. This rejection appears to lack merit. The terms "closed" or "partially closed" nowhere appeared in previously pending claims 1 and 22. To the extent that the rejection was premised on purported confusion over the meaning of the term "second layer," the claims have been amended to replace the "second layer" with "second sheet." There can be no confusion as to the concept that the second sheet may comprise multiple layers – e.g., a backing layer and a peelable film. Accordingly, it is respectfully requested that the rejection of claims 14 and 34 under 35 U.S.C. 112, second paragraph, be withdrawn.

D. Rejections Under 35 U.S.C. § 102

The December 28, 2005 Office Action contained various claim rejections under 35 U.S.C. § 102(b), as summarized below:

- Claims 1, 2, 5, 6, 10, 14, 17-22, 25-26, 30, 34, 37-41, and 43-46 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,055,672 to Hirsch et al. ("Hirsch"); and
- Claims 1, 2, 5-11, 17-22, 25-31, 40, and 43-46 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,418,022 to Anderson et al. ("Anderson").

As applied to the amended claims provided herewith, the above-mentioned claim rejections under 35 U.S.C. 102(b) are traversed for the reasons provided below.

1. Law Regarding Anticipation

In order for a §102(b) rejection of claims to be legally proper, the single cited reference must meet the criteria stated in MPEP §706.02, i.e., the cited reference:

"must teach every aspect of the claimed invention either explicitly or implicitly. Any feature not directly taught must be inherently present." (MPEP §706.02, Rejection on Prior Art [R-1]).

The governing law of CAFC decisions is consistent with such MPEP standard:

“Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. v. Garlock*, 721, F.2d 1540, 220 USPQ 303 at 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). It is not enough that the prior art reference disclose all the claimed elements in isolation. Rather, “anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). Further, “[u]nder 35 U.S.C. § 102, anticipation requires that ... the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.” *Akzo, N.V. v. United States Int’l Trade Comm’n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

2. Patentability of Claims 1, 2, 5, 6, 10, 14, 17-22, 25-26, 30, 34, 37-41, and 43-46 Over Hirsch

Claims 1, 2, 5, 6, 10, 14, 17-22, 25-26, 30, 34, 37-41, and 43-46 include two independent claims – namely, claims 1 and 22. As amended, independent claims 1 and 22 each require, *inter alia*, “a **pressurization gas inlet adapted to permit the ingress of pressurization gas to the enclosed interior volume.**”

Hirsch discloses a package for controlling the atmospheric condition of a packaged (e.g. perishable meat) product. One package wall is formed of a gas impermeable material and a second package wall includes a composite of an inner gas permeable layer and an outer gas impermeable layer that may be removed from the inner gas permeable layer to permit gases to flow through the inner layer and thereby change the atmospheric condition of the packaged product. Hirsch fails to teach or suggest any “pressurization gas inlet adapted to permit the ingress of pressurization gas to [an] enclosed interior volume.” To the contrary, Hirsch teaches that the package is first evacuated, then optionally filled with gas, and finally sealed - with no structure such as pressurization gas inlet, such as that would permit the ingress of pressurization gas for purposes testing the integrity of a seal *after* such a seal is formed. See the following passages excerpted from Hirsch:

The package 10 may be evacuated or filled with an inert gas before sealing thereby eliminating oxygen within the package and reducing bacterial and mold growth so that the shelf-life of the product 28 may be extended for prolonged periods of time.” (Hirsch, col. 4, lines 12-16.)

It is a further feature of the invention to reduce the loose fit normally associated with inert atmosphere packaging by employing an inert gas mixture of nitrogen and carbon dioxide. The carbon dioxide is slowly absorbed into the meat product 28, thus creating a partial vacuum which draws the package lid tightly against the meat product without creating the differential pressures and purging normally associated with high vacuum. (Hirsch, col. 6, lines 28-36.)

The meat containing trays were moved to the sealing station where the multi-layer composite of Example 8 was placed over their open face. The lidding material was heat sealed to the formed tray, affecting a polyethylene to polyethylene seal over most of the circumference of the package, but leaving sufficient unsealed area to affect adequate evacuation. Following the evacuation step, a 50-50 mixture of nitrogen-carbon dioxide was injected and the final seal completed [i.e., *after* addition of gas]. (Hirsch, col. 10, lines 24-33.)

Together with the surgical instrument there was placed into the tray a few drops of an aqueous solution of ethylene oxide. The tray was evacuated, the air replaced with nitrogen, while it was sealed with lidding materials such as specified in examples 8, 9 or 10. Because of the presence of ethylene oxide, the surgical instrument remains sterile as long as the package is in a sealed condition. (Hirsch, col. 10, lines 58-65.)

Hirsch therefore teaches formation of a seal after evacuating and/or adding gas to a package – without teaching any structure permitting gas to be added to a package (e.g., for seal integrity testing) after a seal is formed. Since Hirsch fails to disclose “each and every element of the claimed invention, arranged as in the claim,” Hirsch cannot anticipate independent claims 1 and 22. Likewise, since dependent claims 2, 5, 6, 10, 14, 17-21, 25-26, 30, 34, 37-41, and 43-46 all depend from either claim 1 or 22 and therefore include all of the limitations of the base claims, these dependent claims cannot be anticipated by Hirsch. Accordingly, withdrawal of the rejections of these claims under 35 U.S.C. 102(b) is respectfully requested.

3. Patentability of Claims 1, 2, 5-11, 17-22, 25-31, 40, and 43-46 Over Anderson

Claims 1, 2, 5-11, 17-22, 25-31, 40, and 43-46 include two independent claims – namely, claims 1 and 22. As noted previously, amended independent claims 1 and 22 each require, *inter alia*, “a pressurization gas inlet adapted to permit the ingress of pressurization gas to the enclosed interior volume.”

Anderson discloses microbial resistant packaging wherein at least a portion of a spunbonded olefin sheet material is deformed to increase its surface area to create a pocket to envelop a medical supply or product,

without compromising resistance to penetration by contaminating microorganisms. **Nothing in Anderson teaches pressurization of the interior volume of a package, much less a pressurization gas inlet permitting such pressurization.**

Since Anderson fails to disclose "each and every element of the claimed invention, arranged as in the claim," Hirsch cannot anticipate independent claims 1 and 22. Likewise, since dependent claims 2, 5-11, 17-21, 25-31, 40, and 43-46 all depend from either claim 1 or 22 and therefore include all of the limitations of the base claims, these dependent claims cannot be anticipated by Hirsch. Accordingly, withdrawal of the rejections of these claims under 35 U.S.C. 102(b) is respectfully requested.

E. Rejections Under 35 U.S.C. § 103

The December 28, 2005 Office Action contained various claim rejections under 35 U.S.C. § 103, as summarized below:

- Claims 3, 4, 23, and 24 were rejected under 35 U.S.C. § 103 as obvious over Hirsch in view of U.S. Patent No. 5,217,772 to Brown ("Brown");
- Claims 7-9, 11, 27-29, 31, 42, and 47-49 were rejected under 35 U.S.C. § 103 as obvious over Hirsch in view of Anderson; and
- Claims 3, 4, 23, and 24 were rejected under 35 U.S.C. § 103 as obvious over Anderson in view of Brown.

As applied to the amended claims provided herewith, the above-mentioned claim rejections under 35 U.S.C. 103 are traversed for the reasons provided below

1. Law Regarding Obviousness

Three requirements must be met for a *prima facie* case of obviousness under 35 USC § 103. First the prior art reference(s) must teach all of the limitations of the claims. M.P.E.P. § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to produce the claimed invention. M.P.E.P. § 2143.01. Third, a reasonable expectation of success is required. M.P.E.P. § 2143.02. In addition, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on Applicant's disclosure. M.P.E.P. § 2143.

2. Patentability of Claims 3, 4, 23, and 24 Over Hirsch and Brown

Dependent claims 3 and 4 depend from independent claim 1, and dependent claims 23 and 24 depend from independent claim 22. As discussed previously, amended independent claims 1 and 22 each require,

inter alia, “a pressurization gas inlet adapted to permit the ingress of pressurization gas to the enclosed interior volume.” The failure of Hirsch to teach this feature has been discussed previously herein, with such comments incorporated by reference as to the present rejection of claims 3, 4, 23, and 24. The addition of Brown fails to supply the teachings missing in Hirsch necessary to support a rejection under 35 U.S.C. 103 of claims 3, 4, 23, and 24. Brown is directed to an easily openable breather package for surgical elements. Nothing in Brown teaches or suggests any pressurization gas inlet adapted to permit the ingress of pressurization gas to the enclosed interior volume.

Since any combination of Hirsch or Brown fails to teach all of the limitations of the claims, these references fail to support a *prima facie* case of obviousness of claims 3, 4, 23, and 24 pursuant to M.P.E.P. § 2143.03. Accordingly, withdrawal of the rejections of these claims under 35 U.S.C. 103 is respectfully requested.

3. Patentability of Claims 7-9, 11, 27-29, 31, 42, and 47-49 Over Hirsch and Anderson

Dependent claims 7-9, 11, 27-29, 31, 42, and 47-49 depend from either independent claim 1 or 22. As discussed previously, amended independent claims 1 and 22 each require, *inter alia*, “a pressurization gas inlet adapted to permit the ingress of pressurization gas to the enclosed interior volume.” The failure of both Hirsch and Anderson to teach this feature has been discussed previously herein, with such comments incorporated by reference as to the present rejection of claims 7-9, 11, 27-29, 31, 42, and 47-49. Since any combination of Hirsch and Anderson fails to teach all of the limitations of the claims, these references fail to support a *prima facie* case of obviousness of claims 7-9, 11, 27-29, 31, 42, and 47-49 pursuant to M.P.E.P. § 2143.03. Accordingly, withdrawal of the rejections of these claims under 35 U.S.C. 103 is respectfully requested.

4. Patentability of Claims 3, 4, 23, and 24 Over Anderson and Brown

Dependent claims 3 and 4 depend from independent claim 1, and dependent claims 23 and 24 depend from independent claim 22. As discussed previously, amended independent claims 1 and 22 each require, *inter alia*, “a pressurization gas inlet adapted to permit the ingress of pressurization gas to the enclosed interior volume.” Additionally, the failure of Anderson and Brown to teach this feature has been discussed previously herein, with such comments incorporated by reference as to the present rejection of claims 3, 4, 23, and 24. Since any combination of Anderson and Brown fails to teach all of the limitations of the claims, these references fail to support a *prima facie* case of obviousness of claims 3, 4, 23, and 24 pursuant to M.P.E.P. § 2143.03. Accordingly, withdrawal of the rejections of these claims

under 35 U.S.C. 103 is respectfully requested.

F. Patentability of New Claims

New claims 80-87 all depend from, and therefore include all the limitations of, independent claims 1 or 22. Since claims 1 and 22 have already been patentably distinguished over Hirsch, Anderson, and Brown has already been discussed herein, new claims 80-87 are likewise patentably distinct and should be allowed.

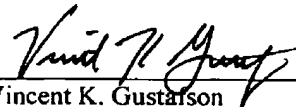
G. (No) Excess Claim Fees

By the present amendment, eight dependent claims (80-87) have been added. However, nine dependent claims (i.e., claim numbers 12, 13, 15, 16, 17, 32, 33, 35 and 36) for which claim fees were previously paid have been cancelled from the application. Accordingly, it is believed that no excess claims fees are due and payable with the present amendment. If Applicants are incorrect in this belief, however, then the Office is hereby authorized to charge Deposit Account No. 08-3284 for any necessary fees to enter this amendment.

CONCLUSION

Based on the foregoing, all of applicants' pending claims 1-11, 14, 18-31, 34, 37-49, and 80-87 are therefore patently distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,



Vincent K. Gustafson
Reg. No. 46,182
Attorney for Applicants

INTELLECTUAL PROPERTY/
TECHNOLOGY LAW
P.O. Box 14329
Research Triangle Park, NC 27709
Telephone: (919) 419-9350
Fax: (919) 419-9354
Attorney Ref: 2771-624 RCE (7497)

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